## PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY	PCT			
To: GLAXOSMITHKLINE Corporate Intellectual Committivine Attn. Kondo, Rie 980 Great West R Brentford Middlesex TW8 9Gs UNITED KINGDOM  GLAXOSMITHKLINE GlaXoSmithKline Comporate IP Received ERENTFORD 2 7 OCT 2004				
IBM : N/A ON OBSTEDORY (E	(PCT Rule 44.1)  Oper of mailing Iday/month/year)  27/10/2004			
Applicant's or agent's file reference  JNR/PB60389C	FOR FURTHER ACTION See paragraphs 1 and 4 below			
International application No. PCT/EP2004/007808	International filing date (day/month/year) 09/07/2004			
Applicant GLAXO GROUP LIMITED				
Authority have been established and are transmitted herewill  Filing of amendments and statement under Article 19: The applicant is entitled, if he so wishes, to amend the claim  When? The time limit for filing such amendments is norr  International Search Report; however, for more  Where? Directly to the International Bureau of WIPO, 34  1211 Geneva 20, Switzerland, Fa  For more detailed instructions, see the notes on the accolor of the international search Article 17(2)(a) to that effect and the written opinion of the international search that regard to the protest against payment of (an) addition the protest together with the decision thereon has been	as of the International Application (see Rule 46): mally 2 months from the date of transmittal of the details, see the notes on the accompanying sheet. chemin des Colombettes scimile No.: (41–22) 740.14.35 mpanying sheet.  report will be established and that the declaration under iternational Searching Authority are transmitted herewith. nal fee(s) under Rule 40.2, the applicant is notified that: In transmitted to the International Bureau together with the test and the decision thereon to the designated Offices. Ilicant will be notified as soon as a decision is made.  e international application will be published by the publication, a notice of withdrawal of the international ureau as provided in Rules 90 bis.1 and 90 bis.3, respectively, and publication.  written opinion of the International Searching Authority to the			
international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.  Within 19 months from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later); otherwise, the applicant must, within 20 months from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.  In respect of other designated Offices, the time limit of 30 months (or later) will apply even if no demand is filed within 19 months.  See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the PCT Applicant's				
Guide, Volume II, National Chapters and the WIPO Internet site.				
Name and mailing address of the International Searching Authority  European Patent Office, P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer  Trudy Hinterwimmer			

Form PCT/ISA/220 (January 2004)

(See notes on accompanying sheet)

#### NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the PCT Applicant's Guide, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions respectively.

#### **INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19**

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only.

#### What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

#### When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

#### Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been as filed, see below.

#### How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as fied.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally fited.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

#### What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

Notes to Form PCT/ISA/220 (first sheet) (January 1994)

BNSDOCID: <XS\_\_\_\_ISA220NOENP4\_I\_>

#### NOTES TO FORM PCT/ISA/220 (continued)

The letter must indicate the differences between the claims as filed and the claims as amended, it must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.

# The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

- [Where originally there were 48 claims and after amendment of some claims there are 51]:
  "Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
- [Where originally there were 15 claims and after amendment of all claims there are 11]:
   \*Claims 1 to 15 replaced by amended claims 1 to 11.\*
- 3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]: "Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or "Claims 7 to 13 cancelled; new claims 15, 16 and 17 added: all other claims unchanged."
- 4. [Where various kinds of amendments are made]: "Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

#### "Statement under article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international appplication is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

#### Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the same time of filing the amendments with the International Bureau, also file a copy of such amendments with the International Preliminary Examining Authority (see Rule 62.2(a), first sentence).

#### Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, where upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see Volume II of the PCT Applicant's Guide.

Notes to Form PCT/ISA/220 (second sheet) (January 1994)

BNSDOCID: <XS\_\_\_\_ISA220NOENP4\_1\_>

## **PATENT COOPERATION TREATY**

# PCT

## **INTERNATIONAL SEARCH REPORT**

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	FOR FURTHER	see Form PCT/ISA/220
JNR/PB60389C	ACTION	as well as, where applicable, item 5 below.
International application No.	International filing date (day/month/ye	ar) (Earliest) Priority Date (day/month/year)
PCT/EP2004/007808	09/07/2004	11/07/2003
Applicant		
GLAXO GROUP LIMITED	<del> </del>	
This International Search Report has been according to Article 18. A copy is being tra	n prepared by this International Searchi Insmitted to the International Bureau.	ng Authority and is transmitted to the applicant
This International Search Report consists	of a total of sheets	
X It is also accompanied by	a copy of each prior art document cited	in this report.
	international search was carried out on ess otherwise indicated under this item.	the basis of the international application in the
The international this Authority (Rul	search was carried out on the basis of a e 23.1(b)).	translation of the International application furnished to
b. With regard to any nucleo	<b>etide and/or amino acid sequence</b> dis	closed in the international application, see Box No. I.
2. X Certain claims were four	nd unsearchable (See Box II).	
3. Unity of invention is lack	king (see Box III).	
4. With regard to the title,		
X the text is approved as su	bmitted by the applicant.	
the text has been establish	ned by this Authority to read as follows:	
5. With regard to the abstract,		
the text is approved as sul	omitted by the applicant.	
the text has been establish	ned, according to Rule 38.2(b), by this A	uthority as it appears in Box No. IV. The applicant
may, within one month froi	m the date of mailing of this internationa	Il search report, submit comments to this Authority.
6. With regards to the drawings,		
a. the figure of the drawings to be p	ublished with the abstract is Figure No.	3
X as suggested by the	• •	
=	s Authority, because the applicant failed s Authority, because this figure better ch	
	published with the abstract.	aradionzes die myenden.

Form PCT/ISA/210 (first sheet) (January 2004)

### **INTERNATIONAL SEARCH REPORT**

International Application No

		PCT/EP200	04/007808
A. CLASSI IPC 7	FICATION OF SUBJECT MATTER A61J7/02 A61J7/04		
According to	o International Patent Classification (IPC) or to both national classific	ation and IPC	
B. FIELDS	SEARCHED		
Minimum do IPC 7	ocumentation searched (classification system followed by classification A61J B65D	ion symbols)	
Documenta	tion searched other than minimum documentation to the extent that	such documents are included in the fields s	earched
Electronic d	ata base consulted during the international search (name of data ba	ise and, where practical, search terms use	d)
C. DOCUMI	ENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the rel	levant passages	Relevant to claim No.
Х	EP 0 629 563 A (LILLY INDUSTRIES 21 December 1994 (1994-12-21)	,	1-4, 7-10, 15-23,29
x	page 3, column 43 - page 4; figur  US 5 805 051 A (WANG SUNWAY R ET 8 September 1998 (1998-09-08)		1-18
	column 3, line 52 - column 5, line figures 1-7	·	
X	DE 39 24 016 A (UNION PHARMA SCIE 22 February 1990 (1990-02-22) column 1 - column 3, line 12; fig	•	1-4,8
		-/	
X Furth	ner documents are listed in the continuation of box C.	χ Patent family members are listed	in annex.
l '	tegories of cited documents :	*T* later document published after the into or priority date and not in conflict with	the application but
considered to be of particular relevance invent		cited to understand the principle or th invention  *X* document of particular relevance; the	claimed invention
*L* docume which i	and which may throw doubts on priority claim(s) or is caled to establish the publication date of another or other special reason (as specified)	cannot be considered novel or canno involve an inventive step when the do  "Y" document of particular relevance; the cannot be considered to involve an in-	cument is taken alone claimed invention
*O* document referring to an oral disclosure, use, exhibition or other means document is comments, such comments, such comments of the international filing date but		document is combined with one or m ments, such combination being obvio in the art.	ore other such docu- us to a person skilled
later th	an the priority date claimed	*&* document member of the same patent  Date of mailing of the international sea	
	8 October 2004	27/10/2004	
Name and m	nailing address of the ISA	Authorized officer	
	European Patent Office, P.B. 5818 Patentiaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Birlanga Pérez, J	M

Form PCT/ISA/210 (second sheet) (January 2004)

## INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP2004/007808

Citation of document with indication, where appropriate of the relevant passages	Relevant to claim No.
Oración or occamient, mini indication, minore appropriate, or the research passages	nelevant to cidini No.
WO 02/36189 A (ANDERSON GREGOR JOHN MCLENNAN; FARR PHILIP WILLIAM (GB); RAND PAUL KE) 10 May 2002 (2002-05-10) page 19 - page 24 page 35, line 30 - page 39, line 20; figures 1-9	1-20
•	
•	
	·
	1
	MCLENNAN; FARR PHILIP WILLIAM (GB); RAND PAUL KE) 10 May 2002 (2002-05-10) page 19 - page 24 page 35, line 30 - page 39, line 20;

2

International application No. PCT/EP2004/007808

## **INTERNATIONAL SEARCH REPORT**

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)
This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:
1. X Claims Nos.: 30, 31 because they relate to subject matter not required to be searched by this Authority, namely:
Rule 6.2 (a)
Claims Nos.:     because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).
Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)
This International Searching Authority found multiple inventions in this international application, as follows:
As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
Remark on Protest  The additional search fees were accompanied by the applicant's protest.  No protest accompanied the payment of additional search fees.
Form PCT/ISA/010 (continuation of first shoot /01) / Inquient 2004)

Form PCT/ISA/210 (continuation of first sheet (2)) (January 2004)

## INTERNATIONAL SEARCH REPORT

information on patent family members

International Application No PCT/EP2004/007808

Patent document cited in search report		Publication date		Patent family member(s)	Publication date
EP 0629563	A	21-12-1994	CA	2125930 A1	18-12-1994
			EP	0629563 A1	21-12-1994
			JP	7137775 A	30-05-1995
US 5805051	Α	08-09-1998	US	6239440 B1	29-05-2001
DE 3924016	Α	22-02-1990	FR	2635214 A1	09-02-1990
			BE	1005278 A0	15-06-1993
			CH	680065 A5	15-06-1992
			DE	3924016 A1	22-02-1990
			ES	2017553 A6	16-02-1991
			ΙT	1233080 B	14-03-1992
WO 0236189	Α	10-05-2002	AU	1233002 A	15-05-2002
			ΑU	1825002 A	15-05-2002
			BR	0115094 A	07-10-2003
			CA	2427145 A1	10-05-2002
			CN	1481263 T	10-03-2004
			CZ	20031208 A3	18-02-2004
			WO	0236188 A2	10-05-2002
			WO	0236189 A1	10-05-2002
			EP	1330281 A1	30-07-2003
			EP	1330282 A2	30-07-2003
			HU	0301446 A2	29-09-2003
			JP	2004512146 T	22-04-2004
			JP	2004512147 T	22-04-2004
			NO	20031915 A	29-04-2003
		•	TW	559561 B	01-11-2003
			US	2004099676 A1	27-05-2004
			US	2004094152 A1	20-05-2004

Form PCT/ISA/210 (patent family annex) (January 2004)